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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/621,760	
	Filing Date	07/17/2003	
	First Named Inventor	Lewis, David	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	>100	Attorney Docket Number	Mirus.030.09.2

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">Remarks</div>	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Mark K. Johnson
Signature	
Date	02/11/2005

CERTIFICATE OF TRANSMISSION/MAILING

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Typed or printed name	Kirk Ekena		
Signature		Date	02/11/2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : **10/621,760**

Applicants : **Lewis, David et al.**

Filed : **07/17/2003**

Art Unit :

Examiner :

Docket No. : **Mirus.030.09.2**

For: **COMPOSITIONS AND PROCESSES USING SIRNA, AMPHIPATHIC COMPOUNDS AND POLYCATIONS**

Commissioner of Patents
PO Box 1450
Alexandria, VA 2231-1450

INFORMATIONAL STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449.

US patent

<u>Patent No.</u>	<u>Applicant</u>	<u>Issue date</u>
5,744,335	Wolff, Jon et al.	04/28/1998
6,180,784	Wolff, Jon et al.	01/30/2001

US application publication

<u>Publication No.</u>	<u>Applicant</u>	<u>Publication date</u>
US-2003-0143204	Lewis, David et al.	07/03/2003
US-2003-0125281	Lewis, David et al.	07/03/2003

REFERENCES CITED

1. Bernstein et al., "Role for a bidentate ribonuclease in the initiation step of RNA interference," *Nature*; Jan. 2001, vol. 409, pp. 363-366
2. Caplen et al., "dsRNA-mediated gene silencing in cultured drosophila cells: a tissue culture model for the analysis of RNA interference," *Gene*; 2000, vol. 252, pp. 95-105
3. Caplen et al., "Specific inhibition of gene expression by small double-stranded RNAs in invertebrate and vertebrate systems," *PNAS*; 2001, vol. 98, no. 17.
4. Catalanotto et al., "Gene silencing in worms and fungi," *Nature*; Mar. 2000, vol. 404, p. 245
5. Clemens et al., "The double-stranded RNA-dependent protein kinase PKR: structure and function," *Journal of Interferon and Cytokine Research*; 1997, vol. 17, pp. 503-524
6. Elbashir et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," *Nature*; May 2001, vol. 411, pp. 494-498
7. Elbashir et al., "RNA interference is mediated by 21- and 22-nucleotide RNAs," *Genes and Development*; 2001, vol. 15, pp. 188-200
8. Fagard et al., "AGO1, QDE-2, and RDE-1 are related proteins required for post-transcriptional gene silencing in plants, quelling in fungi, and RNA interference in animals," *PNAS*; Oct. 2000, vol. 97, no. 21, pp. 11650-11654
9. Gao et al., "A novel cationic liposome reagent for efficient transfection of mammalian cells," *Biochemical and Biophysical Research Communications*; Aug. 1991, vol. 179, no. 1, pp. 280-285
10. Hamilton et al., "A species of small antisense RNA in posttranscriptional gene silencing in plants," *Science*; Oct. 1999, vol. 286, pp. 950-952
11. Hammond et al., "An RNA-directed nuclease mediates post-transcriptional gene silencing in drosophila cells," *Nature*; Mar. 2000, vol. 404, pp. 293-296
12. Hammond et al., "Post-transcriptional gene silencing by double-stranded RNA," *Nature*; Feb. 2001, vol. 2, pp. 110-119
13. Ketting et al., "mut-7 of *C. elegans*, required for transposon silencing and RNA interference, is a homolog of Werner syndrome helicase and RnaseD," *Cell*; Oct. 1999, vol. 99, pp. 133-141
14. Leventis et al., "Interactions of mammalian cells with lipid dispersions containing novel metabolizable cationic amphiphiles," *Biochimica et Biophysica Acta.*; 1990, vol. 1023, pp. 124-132
15. Manche et al., "Interactions between double-stranded RNA regulators and the protein kinase DAI," *Molecular and Cellular Biology*; Nov. 1992, vol. 12, no. 11, pp. 5238-5248
16. Minks et al., "Structural requirements of Double-Stranded RNA for the activation of 2', 5'-oligo(A) polymerase and protein kinase of interferon-treated HeLa Cells," *The Journal of Biological Chemistry*; Oct. 1979, vol. 254, no. 30, pp. 10180-10183

17. Parrish et al., "Functional anatomy of a dsRNA trigger: differential requirement for the two trigger strands in RNA interference," Molecular Cell; Nov. 2000, vol. 6, pp. 1077-1087
18. Player et al., "The 2-5 system: Modulation of Viral and cellular processes through acceleration of RNA degradation," Pharmacol. Ther.; 1998, vol. 78, no. 2, pp. 55-113
19. Reidhaar-Olson et al., "The impact of genomics tools on target discovery," Current Drug Discovery; Apr. 2001
20. Sharp "RNAi and double-strand RNA," Genes and Development; 1999, vol. 13, pp. 139-141
21. Sharp et al., "RNA-Interference-2001," Genes and Development; 2001, vol. 15, pp. 485-490.
22. Stark et al., "How cells respond to interferons," Annu. Rev. Biochem.; 1998, vol. 67, pp. 227-264
23. Summerton et al., "Morpholino and phosphorothioate antisense oligomers compared in cell-free and in-cell systems," Antisense and Nucleic Acid Drug Development; 1997, vol. 7, pp. 63-70
24. Svoboda et al., "Selective reduction of dormant maternal mRNAs in mouse oocytes by RNA interference," Development; 2000, vol. 127, pp. 4147-4156
25. Tabara et al., "The rde-1 gene, RNA interference, and transposon silencing in C. elegans," Cell; Oct. 1999, vol. 99, pp. 123-132
26. Tuschl et al., "Targeted mRNA degradation by double-stranded RNA in vitro," Genes and Development; 1999, vol. 13, pp. 3191-3197
27. Wianny et al., "Specific interference with gene function by double-stranded RNA in early mouse development," Nature Cell Biology; Feb. 2000, vol. 2, pp. 70-75
28. Yang et al., "Evidence that processed small dsRNAs may mediate sequence-specific mRNA degradation during in drosophila embryos," Current Biology; 2000, vol. 10, pp. 1191-1200
29. Zamore et al., "RNAi: Double-stranded RNA directs the ATP-dependent cleavage of mRNA at 21 to 23 nucleotide intervals," Cell; Mar. 2000, vol. 101, pp. 25-33

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,


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2/11/2005


Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <small>FEB 11 2005</small>				<i>Application Number</i>	10/621,760
				<i>Filing Date</i>	07/17/2003
				<i>First Named Inventor</i>	Lewis, David
				<i>Art Unit</i>	
				<i>Examiner Name</i>	
<i>Sheet</i>	1	of	2	<i>Attorney Docket Number</i>	Mirus.030.09.2

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number – Kind Code			
		US-5,744,335	04/28/1998	Wolff, Jon A. et al.	
		US-6,180,784	01/30/2001	Wolff, Jon A. et al.	
		US-2003-0143204	07/03/2003	Lewis, David et al.	
		US-2003-0125281	07/03/2003	Lewis, David et al.	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner Initials		Document Number	Publication Date	Country or Patent Office	Class	Sub Class	<u>Transl.</u>
							yes no

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.		T
		Bernstein et al., "Role for a bidentate ribonuclease in the initiation step of RNA interference," Nature; Jan. 2001, vol. 409, pp. 363-366	
		Caplen et al., "dsRNA-mediated gene silencing in cultured drosophila cells: a tissue culture model for the analysis of RNA interference," Gene; 2000, vol. 252, pp. 95-105	
		Caplen et al., "Specific inhibition of gene expression by small double-stranded RNAs in invertebrate and vertebrate systems," PNAS; 2001, vol. 98, no. 17.	
		Catalanotto et al., "Gene silencing in worms and fungi," Nature; Mar. 2000, vol. 404, p. 245	
		Clemens et al., "The double-stranded RNA-dependent protein kinase PKR: structure and function," Journal of Interferon and Cytokine Research; 1997, vol. 17, pp. 503-524	
		Elbashir et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," Nature; May 2001, vol. 411, pp. 494-498	
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		Fagard et al., "AG01, QDE-2, and RDE-1 are related proteins required for post-transcriptional gene silencing in plants, quelling in fungi, and RNA interference in animals," PNAS; Oct. 2000, vol. 97, no. 21, pp. 11650-11654	
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		Hammond et al., "An RNA-directed nuclease mediates post-transcriptional gene silencing in drosophila cells," Nature; Mar. 2000, vol. 404, pp. 293-296	
		Hammond et al., "Post-transcriptional gene silencing by double-stranded	

	RNA," Nature; Feb. 2001, vol. 2, pp. 110-119	
	Ketting et al., "mut-7 of <i>C. elegans</i> , required for transposon silencing and RNA interference, is a homolog of Werner syndrome helicase and RnaseD," Cell; Oct. 1999, vol. 99, pp. 133-141	
	Leventis et al., "Interactions of mammalian cells with lipid dispersions containing novel metabolizable cationic amphiphiles," Biochimica et Biophysica Acta.; 1990, vol. 1023, pp. 124-132	
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	Minks et al., "Structural requirements of Double-Stranded RNA for the activation of 2', 5'-oligo(A) polymerase and protein kinase of interferon-treated HeLa Cells," The Journal of Biological Chemistry; Oct. 1979, vol. 254, no. 30, pp. 10180-10183	
	Parrish et al., "Functional anatomy of a dsRNA trigger: differential requirement for the two trigger strands in RNA interference," Molecular Cell; Nov. 2000, vol. 6, pp. 1077-1087	
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	Reidhaar-Olson et al., "The impact of genomics tools on target discovery," Current Drug Discovery; Apr. 2001	
	Sharp "RNAi and double-strand RNA," Genes and Development; 1999, vol. 13, pp. 139-141	
	Sharp et al., "RNA-Interference-2001," Genes and Development; 2001, vol. 15, pp. 485-490.	
	Stark et al., "How cells respond to interferons," Annu. Rev. Biochem.; 1998, vol. 67, pp. 227-264	
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	Tuschl et al., "Targeted mRNA degradation by double-stranded RNA in vitro," Genes and Development; 1999, vol. 13, pp. 3191-3197	
	Wianny et al., "Specific interference with gene function by double-stranded RNA in early mouse development," Nature Cell Biology; Feb. 2000, vol. 2, pp. 70-75	
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Examiner Signature		Date Considered	
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